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EXAMINER	
MALAMUD, DEBORAH LESLIE	
ART UNIT	PAPER NUMBER
3766	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,431	SANDERS, RICHARD S.	
	Examiner	Art Unit	
	Deborah Malamud	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) *8-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 8-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 27 April 2007.

2. Applicant's election with traverse of group I (claims 1-7) in the reply filed on 27 April 2007 is acknowledged. The traversal is on the grounds that (pages 12-17, "Remarks"), based on the dependent claims of each group, each group was found by the applicant to contain the same utility of the non-elected group. This is not found persuasive because the election was made between the independent claims of each group, which is found to be the main invention of each group. The dependent claims represent further limitation of the invention as claimed by the independent claim, and do not represent elements of the main invention.

3. The traversal is further on the grounds that (page 14, "Remarks) "it is unclear how the subcombination has the utility of distinguishing between different types of cardiac arrhythmia for patient diagnosis while to combination does not. For example, both inventions include detection circuitry or monitoring means, and neither recites distinguishing between different types of cardiac arrhythmia for patient diagnosis." This is not found persuasive because the combination (group IV, claims 38-41) does not require the use of a cardiac electrogram, which the subcombination (group VII, claims 58-62) does. A cardiac electrogram, such as one claimed in group IV, allows for

specific diagnosis of arrhythmias in the heart, based on waveform morphologies and other parameters. Group IV does not require a cardiac electrogram, but merely cardiac activity monitoring, which can be practiced using other means, such as pulse monitoring or blood pressure.

4. The traversal is further on the grounds that (page 15, "Remarks") "the Examiner has failed to provide a reason why performing the methods with leadless electrodes is materially different than doing the same with electrodes on leads, particularly in the context of the Applicant's claims. The Examiner does not explain why the leadless embodiment is materially different or that the absence of leads is of any consequence in the context of the Applicant's claims." This is not found persuasive because though it is well known in the art of implantable electro-stimulators to use both leaded and leadless electrodes, the method of using them is materially different. Different electrode configurations represent different paths of current, such use of an indifferent electrode, a virtual electrode, or a case electrode. Since the applicant does not specify the use of a leaded or leadless electrode in the method as represented by groups V and VI (claims 42-48 and 49-54) respectively, whereas a lead is required by the apparatus of groups I and II, for example, the examiner maintains the position that the methods could be practiced by leaded or leadless electrodes, and do not require the particular limitation of a leaded electrode.

5. The traversal is further on the grounds that (page 16, "Remarks") "even if the respective apparatuses could be used to provide external storage, this is merely an additional feature and does not provide for a materially different process. For example,

remote storage of cardiac signals for review by a physician could be practiced in addition to the process Inventions. Accordingly, merely adding external storage does not materially change the process, as the process is the same process. The Examiner does not explain why the addition of an external storage step with the hypothetical process for use of the respective apparatuses is a materially different process. It appears that they could still basically be the same processes, only with one having a further external storage step." This is not found persuasive because the method claimed by the applicant in groups V and VI (claims 42-48 and 49-54, respectively) simply do not require this step. The methods require recording monitored cardiac activity, while disabling cardiac stimulation therapy, then enabling cardiac rhythm management therapy that includes monitoring cardiac activity and providing cardiac stimulation therapy (claim 42); and the additional step of diagnosing, using stored cardiac event data, a patient as having a condition requiring use of a cardiac stimulation device (claim 49). It is simply not in the scope of either of these groups, as represented by their respective independent claims, to provide for external storage of the detected cardiac data. The process required by system IV (claims 38-41) does require external storage, which can include an external public database, a handheld device, or many other such media, for access by the patient, physician, or other users. The apparatus as claimed by group IV is therefore, as claimed, capable of being used to practice a materially different process.

6. The applicant further points out (pages 16-17, "Remarks") that "the implanted switch is not patient actuable, as contended by the Examiner." The examiner

respectfully disagrees. It is true that an implanted switch is not easily accessible for physical actuation, such as with a finger. Nonetheless, as disclosed by the applicant's own specification, in paragraph 0071 "the cardiac device may communicate with a patient-worn, portable or bed-side communication system or patient actuatable trigger via the communications circuitry (318)." Therefore the examiner considers the implantable actuatable switch to be controlled externally by the patient.

7. Finally, the applicant requested that the examiner supply references to provide how each invention can be shown to have formed a separate subject for inventive effort. A list of example patents is listed below:

a. Leadless electrodes (Bennett et al, U.S. 5,331,966) vs. leaded electrodes (Bardy, 5,314,430)

b. Memory and data transmission (Yerich et al, U.S. 6,456,878) vs. no memory or data transmission (Funke, U.S. 4,312,355)

c. Mode switch (Zhu et al, U.S. 2003/0060850) vs. no mode switch (Fearnot, U.S. 5,040,533)

d. Use of an electrocardiogram for diagnosis (Bennett et al, U.S. 5,331,966) vs. no use of electrocardiogram (Ostroff et al, U.S. 2003/0036778)

8. The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

9. Claim 6 is objected to because of the following informalities: the claim contains the limitation "the memory" in line 2. There is insufficient antecedent basis for this limitation.

10. Claims 8-62 are objected to because of the following informalities: their status indicators do not reflect the withdrawal of these claims due non-elected inventions.

11. Appropriate correction is required.

Response to Arguments

12. Applicant's arguments filed 27 December 2006 have been fully considered but they are not persuasive. The applicant argues (page 14, "Remarks") "*Infinger* (previously cited reference) 'enables the pacer output' "[a]fter applying the cardioversion electrical energy." (Col. 7, Lines 40-42). As such, the energy delivery circuitry of *Infinger* must have been enabled at all stages described, because *Infinger* discloses delivering electrical therapy at all stages described. The *Infinger* reference fails to describe a monitoring mode in which the energy delivery circuitry is disabled." The examiner respectfully disagrees. In the very passage the applicant has cited, previously also cited by the examiner, makes no mention of electrical energy delivered throughout all stages, but rather electrical energy delivered, *and then* entering stages that include mode switching from monitoring to pacing of the heart. Indeed, the examiner can find no mention throughout the Infinger reference of continuously applied electrical energy. It appears, both in the cited passage, and in other locations in the reference, that

electrical cardioversion energy is delivered, then *post-cardioversion demand pacing* of the heart is implemented. In this demand pacing stage, the function of the pacemaker is switched between monitoring enabled/pacing disabled and pacing disabled/monitoring enabled modes.

13. However, the applicant's arguments, see "Remarks" page 14, filed 27 December 2006, with respect to the rejections of claims 1-8 under Infinger have been fully considered and are persuasive. The examiner concedes that on further examination, Infinger does not teach that coupling the cardiac lead to the lead interface at least in part transitions operation of the device from a monitoring mode in which the energy delivery circuitry is disabled, to an energy delivery mode. Therefore, the rejection has been withdrawn. However, upon further consideration, new grounds of rejection are made in view of Duggan (U.S. 5,318,593).

Claim Rejections - 35 USC § 102

14. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

15. In view of the arguments filed 27 December 2006, and the withdrawal of claims 8-62, the rejection of claims 1-3, 5-8, 11-13, 16-23, 25-30, 32-38, 42, 44-46, 49-51, 52-53, 55 and 58-61 under 35 U.S.C. 102(b) as being anticipated by Infinger (U.S. 5,527,345) is withdrawn.

16. Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Duggan (U.S. 5,318,593). Regarding claims 1 and 5, Duggan discloses (col. 7, lines

51-67; Figure 1) a "pacemaker (12) includes a body tissue and fluid resistant casing (13), a first lead (17) coupled to and attached by an electrode to the heart's atrium (40), and a second lead (19) coupled to and attached by an electrode to the patient's ventricle (42). Further, there is shown an external transmitter (10) coupled by a lead (15) to a coil or antenna (16) disposed externally of the patient's body (14), for transmitting RF coupled signals to the internally implanted pacemaker. Further, there is shown a monitor (63) coupled to the transmitter by a lead (59). As will be explained in detail, the transmitter (10) may be actuated to send signals via the lead (15) and the coil (16), to the internally implanted pacemaker (12), whereby its mode of operation may be changed from one mode to another selected mode; thus, the physician can control the type of pacing imposed upon the patient's heart in accordance with the patient's altered condition." The examiner considers this to be an implantable housing; a first electrode coupled to the housing, and a second electrode; a lead interface coupled to the housing, the lead interface configured to receive a cardiac lead; and a controller coupled to the lead interface. Duggan further discloses, (col. 6, lines 4-23) "A lead may be coupled from the pacemaker to a particular portion or heart, e.g., the patient's ventricle or atrium, to some other body tissue, to a mechanical transducer to sense body activity or to a transducer within the pacemaker to sense some condition of the pacemaker, e.g., moisture. By selectively closing one of the select switches, that lead is connected, for example, to stimulate body tissue or to receive a signal indicative of a condition to be monitored. Failure of a lead may be overcome by using redundant leads; upon sensing the failure of one lead, a second lead may be connected from the

pacemaker to the patient's heart to continue tissue stimulation or monitoring. In one illustrative embodiment of this embodiment, there is included a decoder for sensing and decoding digital signals derived from the pacemaker's memory, to generate and apply control signals to close switches, whereby a selected one of the plurality of switches and leads is coupled to the pacer." The examiner considers this to be monitoring circuitry coupled to the first and second electrodes, the first and second electrodes configured for cardiac activity sensing when the device is operated in the monitoring mode; energy delivery circuitry coupled to the first and second electrodes, the first and second electrodes configured for cardiac activity sensing and energy delivery when the device is operated in an energy delivery mode; and a controller transitioning operation of the device from the monitoring mode, in which the energy delivery circuitry is disabled, to the energy delivery mode, in which the energy delivery circuitry is enabled, at least in part in response to coupling the cardiac lead to the lead interface.

17. Regarding claim 2, Duggan discloses (col. 5, lines 42-52) "the pacemaker includes a multiplexer controlled by the microprocessor for selecting one of a plurality of inputs, whereby signals indicative of the patient's heart activity, e.g., the atrial and ventricular heart activity, other body conditions or conditions such as moisture within the pacemaker, may be selectively applied one at a time to be processed by the microprocessor. A selected output of the multiplexer is applied to an A/D converter and scaling amplifier, whereby the input analog signal is converted to a digital signal and scaled to be processed by the processor." The examiner considers this to be detection

circuitry provided in the housing and coupled to the first and second electrodes, the detection circuitry configured to receive the cardiac signals.

18. Regarding claim 3 and 6, Duggan discloses (col. 27, lines 8-24) "the leads could be coupled to heart tissue, other tissue or transducers, to sense the patient's EKG, pulse rate, pulse width, the time of depolarization between the atrium and ventricle, etc. The time of transmission of a depolarization signal is considered to be indicative of the heart's condition and a window is established by a sensing program in accordance with a normal transmission time. If the received signal is outside the limits of such a window, an indication thereof is transmitted externally of the pacemaker. In a data gathering mode, it is contemplated that the latches associated with the associated leads to the heart sites, tissue sites, or transducers are coupled one at a time, by selectively closing the corresponding select switch (330), whereby that data is sent by the receiver (341) to an external monitoring device." The examiner considers this to be transmitting the contents of the memory to a patient-external device in response to receipt of a transmit request signal.

19. Regarding claim 7, Duggan discloses (col. 5, lines 8-17) "there is provided a link between the internally implanted electrical device and an external transmitter, whereby encoded control signals may be transmitted to the internally implanted electrical device, whereby the process effected by the control means is changed or reprogrammed. More specifically, the transmitted control signals may change the address accessed by the microprocessor within the memory, whereby a new process starting at the new address is then executed." The examiner considers this to be a controller that switches the

cardiac device between the monitoring mode and the energy delivery mode in response to a receiver receiving a switch request signal.

Claim Rejections - 35 USC § 103

20. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

21. In view of the arguments received 27 December 2006, and the withdrawal of claims 8-62, the examiner withdraws the rejection of claims 4, 14-15, 31, 39-41,43, 48 and 62 under 35 U.S.C. 103(a) as being unpatentable over Infinger (U.S. 5,527,345) in view of Ideker et al (U.S. 6,205,357); and of claims 9-10, 24, 47, 54 and 56-57 over Infinger (U.S. 5,527,345) is withdrawn.

22. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duggan (U.S. 5,318,593) in view of Ideker et al (U.S. 6,205,357). Duggan discloses the claimed invention except for a programmable filter coupled to the detection circuitry. Ideker however discloses (col. 7, lines 14-20) "electrodes shown in the positions illustrated panel 3A are, as shown in panel 3B, operatively connected to differential amplifiers (42, 42a, 42b, 42c), in turn connected to bandpass filters (44, 44a, 44b, 44c) and sensed event detector circuitry (46, 46a, 46b, 46c), contained in the ICD (40). Amplification and bandpass filtering are followed by sensed event detection." Duggan and Ideker both disclose devices for switching between sensing and stimulating modes. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Duggan's mode-switching and therapy-disabling system with Ideker's

programmable filter in order to eliminate any noise from the sensed signal and prevent a misdiagnosis.

Conclusion

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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